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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,274	09/24/2003	Andy Wolff	26486	3490

7590
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06/25/2008

EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

MAIL DATE	DELIVERY MODE
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06/25/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/668,274

Applicant(s)

WOLFF ET AL.

Examiner

ELIZABETH R. MACNEILL

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18, 20, 25-45, 47, 52-54 and 111-117 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18, 20, 25-45, 47, 52-54 and 111-117 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/03/08.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-4, 11-16, 18, 20, 25-31, 38-43, 45, 47, 52-54, and 115-117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma et al (US 5,584,688) in view of Pfeiler et al (US 5,558,640)

Sakuma et al teaches an oral device for controlled drug release comprising a reservoir (3) containing a drug configured for release into an outer surface of an oral mucosa (the gingiva) via passageway (4) and an oral anchoring element (1/2). See also removable cap (3, Fig 10). See upper portion which is hard and is a biting surface.

Sakuma does not teach an electronic drug release mechanism, but does teach a "micropump" (13, Fig 11).

Pfeiler teaches an implantable element with electronic drug release mechanism (10)

As to claim 2, 3, 18, 29, 30, 45 see control unit processor, release mechanism and power source within (10), Col 3 at line 35); claim 4, 31 see processor/memory (4) which includes "schedules," considered to be a calendar; claim 11-14, 38-41 telemetry units (8, 12, 16); claim 15, 16, 42, 43 sensor unit (9)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the electronic pump and external sensor of Pfeiler with the oral

delivery device of Sakuma to provide a means to controllably release a drug into the oral mucosa.

3. Claims 1-4, 11-16,18,20,25-31,38-43,45,47,52-54, 11-113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cournet et al (US 4,020,558) in view of Pfeiler et al (US 5,558,640)

Cournet et al teaches an oral device for controlled drug release comprising a reservoir (2) containing a drug configured for release into an outer surface of an oral mucosa (the gingiva) and an oral anchoring element (4, 46). See also molar band 46.

Cournet does not teach an electronic drug release mechanism. Instead, Cournet relies on the solubility of the release compound of the drug

Pfeiler teaches an implantable element with electronic drug release mechanism (10)

As to claim 2,3,18,29,30,45 see control unit processor, release mechanism and power source within (10), Col 3 at line 35); claim 4,31 see processor/memory (4) which includes "schedules," considered to be a calendar; claim 11-14,38-41 telemetry units (8,12,16); claim 15,16, 42,43sensor unit (9)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the electronic pump and external sensor of Pfeiler with the oral delivery device of Cournet to provide a means to controllably release a drug into the oral mucosa. Pfeiler allows the user to adjust the drug delivery rate, including allowing bolus doses and doses which respond to a sensed body condition.

4. Claims 5-10 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma/Pfeiler as applied above, and further in view of Feingold (US 4,871,351)

Sakuma/Pfeiler does not teach two local sensors. Feingold teaches an implantable drug delivery device with local sensors. Local sensor (23) indicates a low battery; sensor 30 measures temperature.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sensors of Feingold in order to monitor the battery life and prevent failure of the device and temperature to protect the patient from an electrical malfunction.

5. Claims 5-10 and 32-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cournet /Pfeiler as applied above, and further in view of Feingold (US 4,871,351)

Cournet /Pfeiler do not teach two local sensors. Feingold teaches an implantable drug delivery device with local sensors. Local sensor (23) indicates a low battery; sensor 30 measures temperature.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sensors of Feingold in order to monitor the battery life and prevent failure of the device and temperature to protect the patient from an electrical malfunction.

6. Claims 17 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakuma/Pfeiler as applied above, and further in view of Theeuwes et al (US 5,298,017).

Sakuma/Pfeiler does not teach an iontophoresis device. Theeuwes teaches an iontophoresis device for use in the oral cavity.

It would have been obvious to one ordinary skill in the art at the time the invention was made to use the iontophoresis in order to improve delivery of the drug through the patient's oral tissue.

7. Claims 17 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cournet /Pfeiler as applied above, and further in view of Theeuwes et al (US 5,298,017).

Cournet /Pfeiler do not teach an iontophoresis device. Theeuwes teaches an iontophoresis device for use in the oral cavity.

It would have been obvious to one ordinary skill in the art at the time the invention was made to use the iontophoresis in order to improve delivery of the drug through the patient's oral tissue.

Response to Arguments

8. Applicant's arguments have been considered but are not persuasive. Applicant argues that electronic devices will not be expected to function in the mouth due to a variety of forces. First, the examiner finds that Sakuma's teaching of a "micropump" would suggest an electronic component to one of ordinary skill in the art. Second, the forces the applicant argues which are unique to the mouth are in fact found in a variety

of places in the body, for example the stomach and intestines (mastication, pH, bacteria), and many electronic devices operate in a range of temperatures (devices held outside the body). As to Sakuma and Pfeiler, the area under the gingivia is *within the oral cavity*. Regarding Cournut and Pfeiler, applicant does not argue the combination, only the references individually. Also, an electronic device may be used for slow release, such as basal rate insulin (Pfeiler). The rejections are maintained.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767